

Food and Drug Administration, HHS

§ 868.6885

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6225 Nose clip.

(a) *Identification*. A nose clip is a device intended to close a patient's external nares (nostrils) during diagnostic or therapeutic procedures.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6250 Portable air compressor.

(a) *Identification*. A portable air compressor is a device intended to provide compressed air for medical purposes, e.g., to drive ventilators and other respiratory devices.

(b) *Classification*. Class II (performance standards).

§ 868.6400 Calibration gas.

(a) *Identification*. A calibration gas is a device consisting of a container of gas of known concentration intended to calibrate medical gas concentration measurement devices.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 868.6700 Anesthesia stool.

(a) *Identification*. An anesthesia stool is a device intended for use as a stool for the anesthesiologist in the operating room.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25049, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6810 Tracheobronchial suction catheter.

(a) *Identification*. A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2314, Jan. 14, 2000]

§ 868.6820 Patient position support.

(a) *Identification*. A patient position support is a device intended to maintain the position of an anesthetized patient during surgery.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 868.6885 Medical gas yoke assembly.

(a) *Identification*. A medical gas yoke assembly is a device intended to connect medical gas cylinders to regulators or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a particulate filter.

(b) *Classification*. Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

PART 870—CARDIOVASCULAR DEVICES

Subpart A—General Provisions

Sec.

- 870.1 Scope.
- 870.3 Effective dates of requirement for pre-market approval.
- 870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Cardiovascular Diagnostic Devices

- 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).
- 870.1100 Blood pressure alarm.
- 870.1110 Blood pressure computer.
- 870.1120 Blood pressure cuff.
- 870.1130 Noninvasive blood pressure measurement system.
- 870.1140 Venous blood pressure manometer.
- 870.1200 Diagnostic intravascular catheter.
- 870.1210 Continuous flush catheter.
- 870.1220 Electrode recording catheter or electrode recording probe.
- 870.1230 Fiberoptic oximeter catheter.
- 870.1240 Flow-directed catheter.
- 870.1250 Percutaneous catheter.
- 870.1270 Intracavitary phonocatheter system.
- 870.1280 Steerable catheter.
- 870.1290 Steerable catheter control system.
- 870.1300 Catheter cannula.
- 870.1310 Vessel dilator for percutaneous catheterization.
- 870.1330 Catheter guide wire.
- 870.1340 Catheter introducer.
- 870.1350 Catheter balloon repair kit.
- 870.1360 Trace microsphere.
- 870.1370 Catheter tip occluder.
- 870.1380 Catheter stylet.
- 870.1390 Trocar.
- 870.1425 Programmable diagnostic computer.
- 870.1435 Single-function, preprogrammed diagnostic computer.
- 870.1450 Densitometer.
- 870.1650 Angiographic injector and syringe.
- 870.1660 Indicator injector.
- 870.1670 Syringe actuator for an injector.
- 870.1750 External programmable pacemaker pulse generator.
- 870.1800 Withdrawal-infusion pump.
- 870.1875 Stethoscope.

- 870.1915 Thermodilution probe.

Subpart C—Cardiovascular Monitoring Devices

- 870.2050 Biopotential amplifier and signal conditioner.
- 870.2060 Transducer signal amplifier and signal conditioner.
- 870.2100 Cardiovascular blood flowmeter.
- 870.2120 Extravascular blood flow probe.
- 870.2300 Cardiac monitor (including cardi tachometer and rate alarm).
- 870.2310 Apex cardiograph (vibrocardiograph).
- 870.2320 Ballistocardiograph.
- 870.2330 Echocardiograph.
- 870.2340 Electrocardiograph.
- 870.2350 Electrocardiograph lead switching adaptor.
- 870.2360 Electrocardiograph electrode.
- 870.2370 Electrocardiograph surface electrode tester.
- 870.2390 Phonocardiograph.
- 870.2400 Vectorcardiograph.
- 870.2450 Medical cathode-ray tube display.
- 870.2600 Signal isolation system.
- 870.2620 Line isolation monitor.
- 870.2640 Portable leakage current alarm.
- 870.2675 Oscillometer.
- 870.2700 Oximeter.
- 870.2710 Ear oximeter.
- 870.2750 Impedance phlebograph.
- 870.2770 Impedance plethysmograph.
- 870.2780 Hydraulic, pneumatic, or photoelectric plethysmographs.
- 870.2800 Medical magnetic tape recorder.
- 870.2810 Paper chart recorder.
- 870.2840 Apex cardiographic transducer.
- 870.2850 Extravascular blood pressure transducer.
- 870.2855 Implantable Intra-aneurysm Pressure Measurement System.
- 870.2860 Heart sound transducer.
- 870.2870 Catheter tip pressure transducer.
- 870.2880 Ultrasonic transducer.
- 870.2890 Vessel occlusion transducer.
- 870.2900 Patient transducer and electrode cable (including connector).
- 870.2910 Radiofrequency physiological signal transmitter and receiver.
- 870.2920 Telephone electrocardiograph transmitter and receiver.

Subpart D—Cardiovascular Prosthetic Devices

- 870.3250 Vascular clip.
- 870.3260 Vena cava clip.
- 870.3300 Vascular embolization device.
- 870.3375 Cardiovascular intravascular filter.
- 870.3450 Vascular graft prosthesis.
- 870.3470 Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.